JUN 3 0 2014 K141374

510k Summary
Bicarbonate Calibrator

1.0

SubmittedBy:
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2.0 Dateofpreparation:

May 23rd 2014

3.0 DeviceIdentification:

Proprietary Names: Bicarbonate Calibrator
Common Name: Bicarbonate calibrator
Classification: 862.1150
Product Code: JIT

4.0 PredicateDevice:

Candidate(s)	Predicate	Manufacturer	Docket Number
Bicarbonate Calibrator	DR0070 Lyophilized Chemistry calibrator	Beckman Coulter	K043460

The Bicarbonate Calibrator is substantially equivalent to the product listed above currently in commercial distribution

5.0 Description:

The Bicarbonate Calibrator kit is a two level aqueous preparation of sodium carbonate intended to provide calibration for the Bicarbonate reagent for the calibration of bicarbonate on Beckman AU Coulter analyzers. This is available in the following configurations Cat # OSR6137, OSR6237 and OSR6537. For convenience this is often referred to internally and externally as OSR6x37.

The following is the kit configuration for the Bicarbonate Calibrator:
ODC0019 has 3 vials with 25ml contents for Level 1 and 3 vials with 25ml for Level 2.
The Bicarbonate Calibrator is designed for optimal performance on Beckman Coulter AU analyzers.
The calibrator contains sodium o-phenylphenate tetrahydrate which acts as a preservative. This ingredient is classified as a potential carcinogen and may cause irritation of the eyes, skin and mucous membranes. Product labeling carries the appropriate hazards and warnings.

6.0 IntendedUse:

The Bicarbonate Calibrator is an aqueous preparation of sodium carbonate intended to be used with the Bicarbonate reagent OSR6x37 for the calibration of bicarbonate on Beckman Coulter AU analyzers.

For in vitro diagnostic use only.

7.0 ComparisontoPredicate(s):

The following tables shows similarities and differences between the predicate identified in Section 4.0 of this summary.

Similarities		
Feature	Bicarbonate Calibrator ODC0019	Lyophilized Chemistry Calibrator DR0070
Intended Use	The Bicarbonate calibrator is an aqueous preparation of sodium carbonate intended to be used with the Bicarbonate reagent OSR6x37 for the calibration of bicarbonate on Beckman Coulter AU analyzers.	Beckman Coulter Chemistry Calibrators are intended for use when calibrating methods run on the Beckman Coulter AU series of chemistry analyzers.
Levels	2 Levels	2 Levels
Traceability	The Bicarbonate calibrator values are traceable to NIST SRM351	The assigned values for the constituents are traceable to reference materials from NIST.

Differences		
Feature	Bicarbonate Calibrator ODC0019	Lyophilized Chemistry Calibrator DR0070
Matrix Base	Aqueous	Human Serum
Analyte Constituents	Sodium carbonate	Albumin Bicarbonate (C02) Direct Bilirubin Total Bilirubin Calcium Cholesterol Creatinine Glucose Inorganic phosphorous Iron Lactate Magnesium Total protein Triglyceride UIBC Urea Nitrogen (BUN) Uric acid
Form	Liquid	Lyophilized human serum with diluent mixture
Volume	3 x 25ml Level 1 3 x 25ml Level 2	12 x 5ml Level 1 12 x 6ml Diluent

Volume	3 x 25ml Level 1 3 x 25ml Level 2	12 x 5ml Level 1 12 x 6ml Diluent 12 x 5ml Level 2 12 x 6ml Diluent
Storage (Closed/ Shelf Life)	13 months	36 months
Open Vial	30 days @ 15-25^{0}C	3 days @ 2-8^{0}C

8.0 Performance Characteristics summary report as per FDA guidance " Abbreviated 510 (k) submissions for In Vitro Diagnostic Calibrators"

4.1 Stability testing summary – include EP25

Stability studies have been performed to determine the open vial stability and shelf life for this calibrator. For Open Vial stability Beckman Coulter utilized internal test procedures from CLSI EP25A entitled "Evaluation of stability of In Vitro diagnostic reagents". Testing was performed using 3 individual calibrator lots and multiple time points throughout the open vial stability claim period on a representative AU Clinical Chemistry analyzer platform.

At each time point the test vial was run with freshly opened calibrator vial. 2 Levels of an appropriate control material were used to control the runs. All were tested in replicated of 5 at each time point. The controls were required to recover within target ranges and meet precision claims (≤ 3% or ≤3% or SD ≤1mEq/L).

Open Vial stability:

- 30 days @ 15-25^{0}C

Shelf Life stability testing was carried out utilizing EP25A in order to support shelf life storage claim of 13 months when stored at 15-25^{0}C. Real time stability testing was performed on 3 individual lots of calibrator at multiple time points. All testing was conducted on a representative AU Clinical Chemistry analyzer platform with the associated reagent test system. The controls were required to recover within target ranges and meet precision claims (≤ 3% or ≤3% or SD ≤1mEq/L). To ensure robustness of the shelf life claim the shelf life period was tested for 13 months plus at least one month after expire date claim.

Shelf Life stability:

- 13 months @ 15-25^{0}C

4.2 Value Assignment Summary

Verification of target values was performed on a representative AU Clinical chemistry analyzer platform. Testing was performed using one approved lot of DR0070 calibrator with OSR6x37 Bicarbonate reagent. The run is controlled with 3 levels of appropriate control material (n=5).

A sample from test calibrator and NIST SRM 351 standard was run (n=10).A maximum allowable deviation of ±5% from assigned targets was applied.

4.3 Traceability Summary

The Bicarbonate Calibrator is manufactured so that the values for the calibrator are traceable to NIST standard reference material SRM351. 2 levels NIST351 standard were prepared stoichimetrically as per certificate of analysis with a concentration of 20mEq/l and 40mEq/L. The bicarbonate calibrator is manufactured from commercially available high purity sodium carbonate and assigned a target value of 20mEq/L and 40mEq/L. Bicarbonate test system is calibrated with reference calibrator and the NIST351 standard and test calibrator recovered (n=10). A maximum allowable deviation of ±5% from assigned targets was applied.

9.0 Conclusion:

The conclusions drawn from the nonclinical tests (discussed above) demonstrate that the Bicarbonate Calibrator ODC0019 is as safe, as effective and performs as well as the predicate device. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 30, 2014

BECKMAN COULTER IRELAND, INC
C/O DAVID DAVIS
250 S. KRAEMER BLVD. E1. SE. 01
BREA CA 92821

Re: K141374
Trade/Device Name: Bicarbonate Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: May 23, 2014
Received: May 27, 2014

Dear Mr. David Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141374

Device Name
Bicarbonate Calibrator

Indications for Use *(Describe)*
The Bicarbonate Calibrator is an aqueous preparation of sodium carbonate intended to be used with the Bicarbonate reagent OSR6x37 for the calibration of bicarbonate on Beckman Coulter AU analysers. For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

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